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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Start-Up Exclusive Evaluation Option License Agreement:

Nitric Oxide (NO) Releasing Materials for Use in Medical Devices Related to Microbial

Management and Wound Care

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: This is notice, in accordance with 35 U.S.C. 209 and 37 CFR part 404, that the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of a Start-Up Exclusive Evaluation Option License Agreement to iFyber LLC, a company having a place of business in Ithaca, New York to practice the inventions embodied in the following patent applications and patents:

- 1. U. S. Patent 7,968,664, issued June 28, 2011, titled "Nitric Oxide Releasing" Diazenium diolated Acrylonitrile-Based Polymers, And Compositions, Medical Devices, And Uses Thereof" [HHS Ref. No. E-188-2004/0-US-06];
- 2. U. S. Patent 8,093,343, issued January 10, 2012, titled "Nitric Oxide-Releasing" Diazenium diolated Compounds" [HHS Ref. No. E-188-2004/0-US-08];

- European Patent Application 05802080.1, filed September 27, 2005, titled "Nitric Oxide Releasing Diazeniumdiolated Acrylonitrile-Based Polymers, And Compositions, Medical Devices, And Uses Thereof" [HHS Ref. No. E-188-2004/0-EP-05];
- Canadian Patent 2581939, issued January 8, 2013, titled "Nitric Oxide Releasing Diazeniumdiolated Acrylonitrile-Based Polymers, And Compositions, Medical Devices, And Uses Thereof" [HHS Ref. No. E-188-2004/0-CA-04];
- Australian Patent Application 2005289414, filed September 27, 2005, titled
 "Nitric Oxide Releasing Diazeniumdiolated Acrylonitrile-Based Polymers, And
 Compositions, Medical Devices, And Uses Thereof" [HHS Ref. No. E-188 2004/0-AU-03]; and
- 6. Australian Patent 2011200972, issued July 5, 2012, titled "Nitric Oxide-Releasing Compounds and Uses Thereof" [HHS Ref. No. E-188-2004/0-AU-07]

The patent rights in these inventions have been assigned to the Government of the United States of America. The territory of the prospective Start-up Exclusive Evaluation Option License Agreement may be worldwide, and the field of use may be limited to:

"Nitric oxide (NO) releasing materials for use in medical /surgical tubing and attachment devices related to tubing; and wound healing devices, including wound dressings/bandages."

Upon the expiration or termination of the Start-up Exclusive Evaluation Option

License Agreement, iFyber will have the exclusive right to execute a Start-up Exclusive

Patent License Agreement which will supersede and replace the Start-up Exclusive

Evaluation Option License Agreement, with no greater field of use and territory than granted in the Start-up Exclusive Evaluation Option License Agreement.

DATES: Only written comments and/or applications for a license which are received by the NIH Office of Technology Transfer on or before [INSERT DATE 15 DAYS FROM DATE OF PUBLICATION OF NOTICE IN THE FEDERAL REGISTER] will be considered.

ADDRESSES: Requests for copies of the patents, patent applications, inquiries, comments, and other materials relating to the contemplated Start-Up Exclusive Evaluation Option License Agreement should be directed to: Betty B. Tong, Ph.D., Senior Licensing and Patenting Manager, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852-3804; Telephone: (301) 594-6565; Facsimile: (301) 402-0220; E-mail: tongb@mail.nih.gov. A signed confidentiality nondisclosure agreement will be required to receive copies of any patent applications that have not been published or issued by the United States Patent and Trademark Office or the World Intellectual Property Organization.

SUPPLEMENTARY INFORMATION: The subject invention describes a family of polymers based on poly(acrylonitrile) that are capable of storing Nitric oxide (NO) bound in a stable chemical functionality, called a diazenium diolate group, and releasing NO under aqueous conditions. The incorporation of these NO-releasing diazenium diolated acrylonitrile- based compositions into suitable, biocompatible dressings could be used to

treat wounds to fight infection, modulate inflammation, and promote angiogenesis and collagen synthesis in order to accelerate wound closure and/or otherwise improve functional outcomes. These polyacrylonitrile-based products could be useful in conjunction with medical devices where the many therapeutic actions of NO would be beneficial.

The prospective Start-up Exclusive Evaluation Option License Agreement and a subsequent Start-up Exclusive Patent License Agreement may be granted unless the NIH receives written evidence and argument, within fifteen (15) days from the date of this published notice, that establishes that the grant of the contemplated Start-up Exclusive Evaluation Option License Agreement would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR part 404.

Complete applications for a license in the prospective field of use that are filed in response to this notice will be treated as objections to the grant of the contemplated Start-Up Exclusive Evaluation Option License Agreement. Comments and objections submitted in response to this notice will not be made available for public inspection and, to the extent permitted by law, will not be released under the Freedom of Information Act, 5 U.S.C. 552.

Dated:

May 12, 2014

Richard U. Rodriguez,
Director,
Division of Technology Development and Transfer,
Office of Technology Transfer,
National Institutes of Health.

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